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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HML2/0918

EXAMINER

FLOOD, M

ART UNIT	PAPER NUMBER
1651	<i>[Signature]</i>

DATE MAILED:

09/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/781,301	Applicant(s)	Applicant
Examiner Michele Flood	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Jul 5, 2001
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 20) Other: _____

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DETAILED ACTION

Election/Restriction

Acknowledgment is made of applicant's election of Group I, Claims 1-15, without traverse, and Claims 16-17 are withdrawn from further consideration by the examiner as an non-elected invention. Further acknowledgment is made of applicant's election of the species *Serenoa*.

Claims 1-15 are under examination.

The claims have been examined insofar as they read on the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is rendered vague and indefinite by the phrase "which can form a complex with the active ingredients, thereby improving absorption or effectiveness" because it is uncertain as to what is the subject matter applicant intends to direct the invention. For instance, it is unclear as to

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what "effectiveness" is improved by the complex formed. The lack of clarity makes the claim ambiguous.

Claim 13 recites the limitation "derivative". One of ordinary skill in the art would not know how to interpret the metes and bounds of this limitation. A derivation of a chemical compound may be closely patterned after the subject chemical compound or may be loosely patterned after the subject chemical compound, such that it may bear no resemblance or form recognizable as the subject chemical compound which maybe chemically and/or biologically unrelated in function or form to the subject chemical compound. Applicant may overcome the rejection by replacing "derivative" with an active derivative thereof, wherein the active derivative has the same activity of said compound X.

All other claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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Claims 1-2 and 9-13 are rejected under 35 U.S.C. 102(b)/102(e) as being anticipated by Soler et al. (A or N).

Applicant claims a cosmetic composition comprising an active ingredient comprising a fatty acid or an antiandrogenic sterol from *Serenoa* or from *Cucurbita* seeds in a therapeutically effective amount sufficient to provide a retarding action on the growth of superfluous hair.

Applicant further claims a composition, further comprising anti-inflammatory or vasal protective agents, wherein the active ingredient(s) are present in an amount from about 0.1% to about 3% by weight. Applicant further claims a composition, wherein the composition is in the form of a liquid, a solid, or a semi-solid. Applicant further claims a composition, wherein the composition is in the form of a lotion, a milk, a solution, an emulsion, a cream, a paste, a gel, a foam, or a combination thereof. Applicant further claims a composition, which further comprises one or more conventional depilatory agents. Applicant further claims a composition, wherein the one or more conventional depilatory agents comprise a thiol derivative; thioglycolic or thiolactic acid, or an alkali or alkaline-earth metal salt thereof; ethanolamine thioglycate; aminoethanethiol; mercaptopropionic acid thioglycic or thioacetic acid; barium sulfate; or a mixture thereof.

Soler (US Patent 6,113,926 relied upon herein for convenience) teaches cosmetic compositions comprising antiandrogenic phytosterols from *Serenoa* in an amount sufficient to retard the growth of superfluous or excess hair growth. The compositions further contain antiinflammatories and chemical depilatories, such as thioglycolic acid and its salts (see Column 3, lines 34-38 and lines 50-57), wherein the active ingredients are in the same amount as instantly

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claimed. The formulations useful to control hair growth are presented as solutions, shampoos, creams, and gels. The reference anticipates the claimed subject matter. The reference anticipates the claimed subject matter.

Claims 1 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Barr (O).

Applicant claims a cosmetic composition comprising an active ingredient comprising a fatty acid or an antiandrogenic sterol from *Serenoa* or from *Cucurbita* seeds in a therapeutically effective amount sufficient to provide a retarding action on the growth of superfluous hair.

Applicant further claims a composition, wherein the active ingredient(s) are present in an amount from about 0.1% to about 3% by weight. Applicant further claims a composition, wherein the composition is in the form of a liquid, a solid, or a semi-solid. Applicant further claims a composition, wherein the composition is in the form of a lotion, a milk, a solution, an emulsion, a cream, a paste, a gel, a foam, or a combination thereof.

Barr teaches pharmaceutical or cosmetic compositions comprising therapeutic effective amounts of lipophilic extracts of *Serenoa repens* for the treatment of hirsutism or overgrowth of hair. The composition may be prepared as creams, foams, liposome emulsions, shampoos or conditioners (See Claim 12). The reference anticipates the claimed subject matter.

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Claims 1 and 9-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Greentech et al. (P).

Applicant claims a cosmetic composition comprising an active ingredient comprising a fatty acid or an antiandrogenic sterol from *Serenoa* or from *Cucurbita* seeds in a therapeutically effective amount sufficient to provide a retarding action on the growth of superfluous hair.

Applicant further claims a composition, wherein the active ingredient(s) are present in an amount from about 0.1% to about 3% by weight. Applicant further claims a composition, wherein the composition is in the form of a liquid, a solid, or a semi-solid. Applicant further claims a composition, wherein the composition is in the form of a lotion, a milk, a solution, an emulsion, a cream, a paste, a gel, a foam, or a combination thereof. Applicant further claims a composition, which further comprises one or more conventional depilatory agents. Applicant further claims a composition, wherein the one or more conventional depilatory agents comprise a thiol derivative; thioglycolic or thiolactic acid, or an alkali or alkaline-earth metal salt thereof; ethanolamine thioglycate; aminoethanethiol; mercaptopropionic acid thioglycic or thioacetic acid; barium sulfate; or a mixture thereof.

Greentech teaches anti-androgenic, cosmetic compositions comprising lipid fractions of *Serenoa repens* (sabal), which are used for prevention of hair growth. The compositions further comprise depilatories such as thioglycolic and thiolactic acids and their salts, flavonoids, and phenols. Greentech teaches the compositions in various forms: cream, gels, lotions, milks, emulsions, liquids, body oils, and shampoos, wherein the active ingredients comprises 0.1 to 20%

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and preferably 2 to 5% of the active ingredients. The reference anticipates the claimed subject matter. The reference anticipates the claimed subject matter.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soler et al. (A or N) or Barr (O), or Greentech et al. (P) in view of Juneja (B), de la Guardia (C), and Molliere et al. (Q).

Applicant claims a cosmetic composition comprising an active ingredient comprising a fatty acid or an antiandrogenic sterol from *Serenoa* or from *Cucurbita* seeds in a therapeutically effective amount sufficient to provide a retarding action on the growth of superfluous hair.

Applicant further claims a composition, which further comprises a conventional depilation accelerator, wherein the conventional depilation accelerator comprises a urea, a thiourea, or a biguanide, or a combination thereof.

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The teachings of Soler, Barr, and Greentech are set forth above. Soler, Barr, and Bellanger teach the claimed invention except for a conventional depilation accelerator, wherein the conventional depilation accelerator is either urea, thiourea, biguanide, or a combination thereof. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instantly claimed conventional depilation accelerators to the compositions taught by either Soler, Barr or Greentech because Juneja, de la Guardia, and Molliere teach conventional depilation accelerators, which are used in the making of depilatory formulations. For instance, Juneja teaches an aqueous depilatory composition comprising biguanide and active thiol agents which provide for faster hair removal; de la Guardia teaches a stable aqueous depilatory composition, comprising alkali metal silicates, alkali earth metal salts of alpha- and/or beta-mercapto carboxylic acids and thiourea; and Molliere teaches accelerating agents for depilatory compositions comprising Ca, Sr, Li or thiolactate, thioglycolate or mercaptocarboxylate, wherein urea and dicyandiamide may also be present. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the conventional depilation accelerators to the compositions taught by Soler, Barr, and Greentech because Juneja, de la Guardia, and Molliere each teach that the referenced conventional depilation accelerators as compositions reduce depilation time, wherein the reduction permits less exposure of skin to possible skin irritation.

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Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soler et al. (A or N) or Barr (O), or Greentech et al. (P) and Barr (O), or Greentech et al. (P) in view of Juneja (B), de la Guardia (C), and Molliereet al. (Q) in view of Bombardelli et al. (AE, EP 028713 A2), Mustich (D), Marissal (E), Bombardelli et al. (AC, WO 00/02570), Lietti et al. (F), Bombardelli et al. (G), and Bombardelli et al. (AB, 4,963,527).

Applicant claims a cosmetic composition comprising an active ingredient comprising a fatty acid or an antiandrogenic sterol from *Serenoa* or from *Cucurbita* seeds in a therapeutically effective amount sufficient to provide a retarding action on the growth of superfluous hair.

Applicant further claims a composition, further comprising anti-inflammatory or vasal protective agents. Applicant further claims a composition, wherein the anti-inflammatory or vasal protective agents comprise at least one of: triterpenes from liquorice; saponins from a horse chestnut plant; triterpenes from *Terminalia sericea*; isobutylamides from *Zanthoxylum bungeanum*; ginkoflavoneglucosides from *Gingko*; polyphenols from grape seeds; anthocyanosides from bilberries; saponins from butcher's broom; or a mixture thereof. Applicant further claims a composition, which comprises a *Serenoa repens* extract and at least two anti-inflammatory or vasal protective agents. Applicant further claims a composition further comprising a pharmaceutically or cosmetically acceptable carrier, excipient, or adjunct, which can form a complex with the active ingredients, thereby improving absorption or effectiveness. Applicant further claims a composition, wherein the carrier comprises a phospholipid. Applicant further claims a composition, wherein the active ingredient(s) are present in an amount from about 0.1%

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to about 3% by weight. Applicant further claims a composition, wherein the composition is in the form of a liquid, a solid, or a semi-solid. Applicant further claims a composition, wherein the composition is in the form of a lotion, a milk, a solution, an emulsion, a cream, a paste, a gel, a foam, or a combination thereof. Applicant further claims a composition, which further comprises one or more conventional depilatory agents. Applicant further claims a composition, wherein the one or more conventional depilatory agents comprise a thiol derivative; thioglycolic or thiolactic acid, or an alkali or alkaline-earth metal salt thereof; ethanolamine thioglycate; aminoethanethiol; mercaptopropionic acid thioglycic or thioacetic acid; barium sulfate; or a mixture thereof.

The combined teaching of Soler, Barr, Bellanger, Barr, Greentech, Juneja, de la Guardia, and Molliere are set forth above. The combined teaching teaches the claimed invention except for the instantly claimed anti-inflammatory or vasal protective agents, and a pharmaceutically or cosmetically acceptable carrier, excipient, or adjunct, which can form a complex with the active ingredients, thereby improving absorption or effectiveness, wherein the carrier comprises a phospholipid. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed conventional ingredients to the compositions taught by the combined teachings of Soler, Barr, Bellanger, Barr, Greentech, Juneja, de la Guardia, and Molliere because at the time the invention was made each of the ingredients were known in the art for their instantly claimed functional effects. For instance, Bombardelli (AE) teaches complexes of triterpene saponins complexed with natural or synthetic phospholipids, wherein the triterpene saponins were extracted from *Aesculus hippocastanum* (horse chestnut plant), *Ruscus aculeatus* (butcher's broom),

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Glycyrriza sp. (liquorice), and *Terminalia species*. The compositions taught by Bombardelli are suitable for use as the active principle in pharmaceutical, dermatologic and cosmetic compositions, and have high lipophilia and improved bioavailability. Moreover, Mustich teaches that horse chestnut saponins have anti-inflammatory and anti-edematous properties, and Marissal teaches that triterpenes from *Terminalia sericea* have cicatrinin and anti-inflammatory properties. Bombardelli (AC) teaches an extract of *Zanthoxylum bungeanum* containing isobutylamides with anti-inflammatory, anti-itching and analgesic activities, which is used in the making of depilatory creams, after-sun formulations, shaving lotions and creams. Lietti teaches bilberry anthocyanidines with anti-inflammatory, vaso-protective properties which can be used in the making of pharmaceutical compositions for topical administration (e.g. ointments, creams, gels and aqueous solutions or suspensions), and used in the treatment of wounds or sores. Finally, Bombardelli (G and AB) also teaches compositions comprising a *Ginkgo biloba* extract/phospholipid complex and *Vitis vinifera* (grape seeds) flavonoids complexed with phospholipids, respectively, which are used in the making of pharmaceutical and cosmetic compositions, and which have improved bioavailability and therapeutic properties. One of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the instantly claimed anti-inflammatory or vasal protective agents, and further add a pharmaceutically or cosmetically acceptable carrier, excipient, or adjunct, which can form a complex with the active ingredients, thereby improving absorption or effectiveness, wherein the carrier comprises a phospholipid to the composition taught by the combined teachings

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of Soler, Barr, Bellanger, Barr, Greentech, Juneja, de la Guardia, and Molliere because at the time the invention was made each of the instantly claimed ingredients were well known in the art for the instantly claimed functional effect, as evidenced by the teachings of Bombardelli, Mustich, Marissal, and Lietti set forth above.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

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the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

MCF

September 13, 2001



CHRISTOPHER R. TATE
PRIMARY EXAMINER